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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/830,189	04/21/2004	Brian S. Kelleher	028US2	7725

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JONATHAN SPANGLER
NU VASIVE, INC.
4545 TOWNE CENTRE COURT
SAN DIEGO, CA 92121

EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	**PAPER NUMBER**
3736	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/830,189	KELLEHER ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/7/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on January 7, 2008 has been entered.

Claim Objections

2. Claims 14 and 18 are objected to because of the following informalities: "said onset electrical stimulus level" lacks antecedent basis in both claims. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-13, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558) in view of Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation).

Neubardt discloses a method for spinal screw insertion and further discloses applying an electrical stimulus to the first aspect of the bone; the electrical stimulus is emitted from an electrode disposed on the distal end of at least one of a probe and surgical tool; applying an electrical stimulus comprises applying a plurality of electrical stimulus pulses; the bone is disposed within one of the cervical, thoracic, and lumbar region of the patient's spine; the spinal nerve exits from successive vertebrae within one of the cervical, thoracic, and lumbar region of the patient's spine; the first aspect of the bone comprises a region within a pedicle in contact with a pedicle screw; and applying an electrical stimulus to the first aspect of the bone comprises applying the electrical stimulus to a proximal end of a bone screw inserted into the first aspect of the bone. See Figures 3 and 4; and Column 8, lines 59-67.

Neubardt however fails to disclose electrically monitoring a muscle myotome associated with the spinal nerve; automatically determining an onset neuro-muscular response to the application of the electrical stimulus to the first aspect of the bone by automatically increasing the electrical stimulus until the onset neuro-muscular response is detected; communicating to a surgeon operating on the patient's spine an onset electrical stimulus level which causes the onset neuro-muscular response; the plurality of electrical stimulus pulses comprises current pulses that increase over time; the plurality of electrical stimulus pulses comprises current pulses that vary incrementally; the plurality of electrical stimulus pulses comprises current pulses varied incrementally within a range from 0.5 to 32.0 milliamps; the onset neuro-muscular response is an electromyography response from a muscle coupled to the spinal nerve; electrically

monitoring the muscle myotome is performed through the use of an electrode electrically coupled to the muscle myotome; the muscle myotome is disposed in one of the patient's legs; and the onset neuro-muscular response is determined by assessing whether the neuro-muscular response is greater than a predetermined onset level and increasing the electrical stimulus until the determined neuro-muscular response is greater than the predetermined onset level.

Calancie et al disclose a means for determining the evoked EMG during spinal fusion surgery and further disclose electrically monitoring a muscle myotome associated with the spinal nerve; automatically determining an onset neuro-muscular response to the application of the electrical stimulus to the first aspect of the bone by automatically increasing the electrical stimulus until the onset neuro-muscular response is detected; communicating to a surgeon operating on the patient’s spine an onset electrical stimulus level which causes the onset neuro-muscular response; the plurality of electrical stimulus pulses comprises current pulses that increase over time; the plurality of electrical stimulus pulses comprises current pulses that vary incrementally; the plurality of electrical stimulus pulses comprises current pulses varied incrementally within a range from 0.5 to 32.0 milliamps; the onset neuro-muscular response is an electromyography response from a muscle coupled to the spinal nerve; electrically monitoring the muscle myotome is performed through the use of an electrode electrically coupled to the muscle myotome; the muscle myotome is disposed in one of the patient's legs; and the onset neuro-muscular response is determined by assessing whether the neuro-muscular response is greater than a predetermined onset level and

increasing the electrical stimulus until the determined neuro-muscular response is greater than the predetermined onset level.. See pages 2780-2782.

Since both Neubardt and Calancie et al disclose means for monitoring stimulus evoked responses, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Neubardt to include the use of electrically monitoring the EMG response, as per the teachings of Calancie et al, since it would provide a more accurate means of monitoring the status of the pedicle screw in relation to the spinal nerve. It also would have been obvious to one of ordinary skill in the art to apply the monitoring means to the arms of the patient when working on the cervical spine.

5. Claims 14 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558) and Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation) as applied to claim 1 above, and further in view of Hacker (6,334,068 B1).

Neubardt and Calancie et al, as discussed above, disclose a means for determining the nerve location through stimulation but fail to disclose communicating to the surgeon includes visually displaying an intensity level representing the onset stimulus level causing the onset neuromuscular response for the spinal nerve; and the visually displaying involves the use of an integrated display.

Hacker discloses an intraoperative neuroelectrophysiological monitor and further discloses communicating to the surgeon includes visually displaying an intensity level representing the onset stimulus level causing the onset neuromuscular response for the

spinal nerve; and the visually displaying involves the use of an integrated display. See Figure 1; Column 4, lines 20-30; Column 8, lines 16-20 and 26-34; and Column 13, lines 29-37.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Neubardt and Calancie et al to include the use of visually displaying the stimulus level, as per the teachings of Hacker, since it would provide a means of alerting the user of the stimulus level.

6. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558), Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation) and Hacker (6,334,068 B1) as applied to claim 14 above, and further in view of Neurovision SE Nerve Locator/Monitor.

Neubardt, Calancie et al and Hacker, as discussed above, disclose a means of monitoring the muscle response of a stimulated nerve during spinal surgery, but fail to disclose illuminating lights; illuminating lights of varying colors; and each color corresponds to a predetermined warning to the user.

Neurovision SE discloses a means for stimulating and locating nerves and further discloses illuminating lights; illuminating lights of varying colors; and each color corresponds to a predetermined warning to the user. See Chapter 6: 6.1 and 6.2.

Since Neubardt, Calancie et al and Hacker disclose means for visually alerting a user to the EMG status, but fail to disclose colored lights representing the measured status, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Neubardt, Calancie et al and Hacker

to include the use of colored lights, as per the teachings of Neurovision SE, since it is well known to utilize colored lights to provide a warning.

7. Claims 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558) and Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation) as applied to claim 1 above, and further in view of Raymond et al (5,284,153).

Neubardt and Calancie et al, as discussed above, disclose a means for monitoring the EMG response to a stimulated pedicle screw, but fail to disclose the use of an audible indicator for indicating an intensity level of the response; sounding an alarm; varying the volume of the alarm; and varying the frequency of the alarm.

Raymond et al disclose a means of protecting nerves from injury during surgery, and further disclose the use of an audible indicator for indicating an intensity level of the response; sounding an alarm; varying the volume of the alarm; and varying the frequency of the alarm. See Column 7, lines 8-16.

Since Neubardt, Calancie et al and Raymond et al disclose means for monitoring the location of a medical instrument relative to a nerve, it would have been obvious to one of ordinary skill in the art to modify the combination of Neubardt and Calancie et al to include the use of an audible indicator, as per the teachings of Raymond et al, since it would provide an additional means of alerting the user.

Response to Arguments

8. Applicant's arguments filed August 2, 2007 have been fully considered but they are not persuasive. The Applicants argue that the currently amended claims overcome the combination of Neubardt and Calancie et al, due to the disclosure of "automatically determining" the onset response and "automatically increasing" the stimulus until the onset response is detected. While the current specification is directed towards using a computer-based means for detecting an onset response and increasing the stimulus to detect the onset response, the current claim language can be interpreted by one of ordinary skill in the art that the “automatically determining” the onset response and the “automatically increasing” the stimulus until the onset response is detected can be performed by the electrophysiologist/neurophysiologist.

In particular, the Applicants argue that Calancie et al fail to overcome the deficiencies of Neubardt because Calancie et al fail to disclose automatically determining an onset response, and also fail to disclose automatically increasing the stimulus until the onset response is detected. Calancie et al clearly disclose having an electrophysiologist determine the onset response through the use of watching for an EMG response, therefore the electrophysiologist has the ability to “automatically determine” the onset response. Calancie et al also clearly disclose automatically increasing the intensity of the stimulus until a response was detected (the onset response)(page 2781, Column 2, lines 12-15), since the electrophysiologist would obviously start with a first stimulus level and if there was no response to that level, the electrophysiologist would then (automatically) increase the stimulus level until a response was received.

The Applicants further argue that Calancie et al also fail to disclose "communicating to a surgeon operating on the patient's spine an onset electrical stimulus level which causes said onset neuro-muscular response". Calancie et al discloses broadcasting EMG signals over a speaker as a means of feedback to the surgeon, and one of ordinary skill in the art would be able to determine that the surgeon would be able to visually verify the stimulus level on the stimulus generator, or have the electrophysiologist verbally announce the stimulus level in response to an audible EMG signal.

Therefore, based on the above arguments above, the current rejection utilizing the combination of Neubardt and Calancie et al is being maintained.

The Applicants then argue that Hacker fails to overcome the deficiencies of the combination of Neubardt and Calancie et al, because Hacker fails to disclose visually displaying to the surgeon an intensity level representing an onset stimulus level causing the onset response for the nerve. Hacker clearly discloses a monitor that comprises a display and a stimulator section for performing EMG studies. One of ordinary skill in the art would have been able to determine the display of Hacker would obviously have to have a visual indication of an applied stimulus level during an EMG study, and therefore would visually display the intensity level to the surgeon. Therefore, the rejection of Claim 14 based on the combination of Neubardt, Calancie et al and Hacker stands.

The Applicants further argue NeuroVision SE fails to overcome the deficiencies of the combination of Neubardt, Calancie et al and Hacker, since NeuroVision SE fails to disclose visually displaying illuminating lights indicative of an intensity level of the

applied stimulus. NeuroVision SE discloses the use of colored LEDs to indicate the operating status of the device. Based on the disclosure of a display in Hacker for displaying information during an EMG study, one of ordinary skill in the art would have been able to utilize the colored LEDs of NeuroVision SE to indicate the intensity level of the stimulus, since the display of Hacker is nothing more than another means of providing an operating status of a device. Therefore, the combination of Neubardt, Calancie et al, Hacker and NeuroVision SE stands.

The Applicants further argue Raymond et al fail to overcome the deficiencies of Neubardt and Calancie et al, because Raymond et al fail to disclose audibly indicating an intensity level representing an onset stimulus. Raymond et al clearly discloses utilizing audio feedback with reference to the electrical stimulus, in Column 17, lines 45-59. Therefore, the combination of Neubardt, Calancie et al and Raymond et al stands.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Primary Examiner, Art Unit 3736